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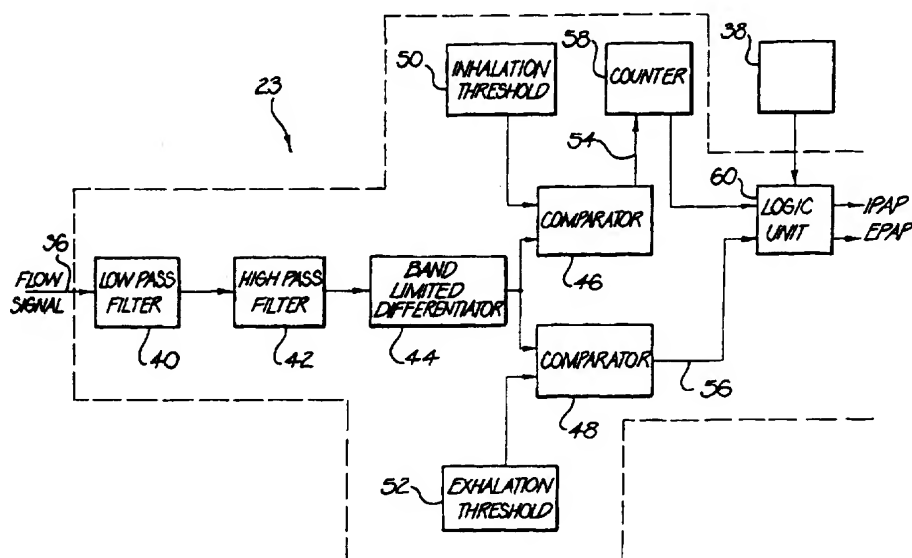
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(54) Title: INSPIRATORY DURATION IN CPAP OR ASSISTED RESPIRATION TREATMENT

## (57) Abstract

Apparatus for the supply of breathable gas cyclically at an inspiratory pressure and the lower expiratory pressure substantially in synchronism with a patient's (16) respiration is disclosed. A flow generator (10) is coupled to a gas delivery system (12) to deliver the breathable gas to the patient's airways. A motor controller (23) receives a signal (36) representing respiratory flow. A motor controller (23) outputs a control signal (24) has control over the electric motor (25) and thus the turbine (22) to generate the required inspiratory and expiratory pressures. The controller (23) detects transitions between inspiration and expiration from the flow signal (36) to discriminate between patient inspiration and expiration. A counter (58) counts a first time duration

commenced from the last transition to inspiration, whereby if the first time duration elapses before a transition to expiration, the controller (23) causes the supply of the expiration pressure. Furthermore, another counter (62) counts a second time duration commenced from the last transition to inspiration that forces the turbine (22) to supply the inspiratory pressure until the second time duration elapses even if during the second time duration there is a transition to expiration by the patient.



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## **Inspiratory Duration in CPAP or Assisted Respiration Treatment**

### **Field of the Invention**

This invention relates to the selection and/or automatic control of IPAP  
5 duration during CPAP or assisted respiration treatment. In preferred non-exclusive  
forms, it relates to the selection of a variable maximum IPAP duration, a variable  
minimum IPAP duration and the automatic adjustment of a variable IPAP duration, or  
combinations of these.

In this specification references to "transitions between inspiration and  
10 expiration" are to be understood as transitions both from inspiration to expiration and  
from expiration to inspiration.

### **Background of the Invention**

The administration of non-invasive CPAP (Continuous Positive Airway  
15 Pressure) is an effective way of treating patients who suffer from OSA (Obstructive  
Sleep Apnea) and upper airway resistance syndrome. CPAP treatment effectively acts  
as a pneumatic splint of the patient's upper airway. Common to all forms of non-  
invasive CPAP apparatus is a nose, mouth or face mask which is fitted to a patient and  
connected to a flow generator via a flexible air delivery tube/conduit. The flow  
20 generator includes an electric motor driving a turbine to supply air or breathable gas for  
the administration of CPAP treatment to the patient during sleep. The positive air  
pressures supplied at the entrance to the patient's airway typically is in the range 2-20  
cm H<sub>2</sub>O.

In bilevel CPAP, the pressure of the delivered air or breathable gas is ideally  
25 switched between two levels coinciding (in synchronism) with patient breathing. The  
pressure required to maintain adequate airway patency is typically substantially higher  
in inspiration than in expiration. Further, the pressure level required during inspiration  
is approximately equal to the single fixed pressure level used in CPAP therapy. This  
observation permits the administration of a lower pressure (referred to as EPAP) in

expiration, and a higher pressure (referred to as IPAP) during inspiration. Therefore, the mean pressure delivered to the patient is reduced compared with CPAP therapy, leading to increased comfort and potential compliance. In some instances bilevel CPAP may also be used to provide respiratory assistance or ventilation. Much of the practical  
5 difficulty in designing CPAP apparatus is the accurate detection of the transition between inspiration to expiration so that synchronism with respiration is maintained.

When bilevel CPAP treatment is employed using only a nose mask, for some patients the higher IPAP pressure can introduce a mouth leak by which air entering the nose escapes via the mouth. The presence of a mouth leak during IPAP makes it  
10 difficult for the CPAP apparatus to accurately detect when the patient exhales. The IPAP pressure therefore may erroneously be maintained during expiration, thereby increasing the work of breathing, possibly leading to an arousal from sleep.

One method of circumventing the problem of mouth-leak is to use a full face mask or a combined nose/mouth mask; however this may lead to discomfort for some  
15 patients and effectively sealing the mask is difficult.

An alternate manner of minimising the effect of mouth-leak is to limit the maximum time for which the CPAP apparatus can remain in the IPAP state. With an appropriate limit on the duration of the IPAP time, the machine eventually 'times-out' and reverts to EPAP treatment pressure if it is unable to detect, as a result of a leak,  
20 that the patient has exhaled. When the patient next inhales, the CPAP apparatus detects this occurrence and reverts to the IPAP treatment pressure.

In all known bilevel CPAP apparatus the IPAP time-out is of a fixed duration, typically three seconds, which is longer than the usual maximum inspiratory time. From clinical trials conducted by the present inventors, it has become apparent that  
25 problems still arise, as it is possible for a patient to take a number of breaths before the time-out occurs. The patient must therefore still breath against the IPAP pressure, so the work of breathing is increased. The benefits of the delivered therapy are therefore diminished and, in some cases, the device may act to the patient's detriment.

The present invention is directed to overcoming or at least ameliorating one or more of the above-mentioned disadvantages.

### Disclosure of the Invention

5 In one broad form, the invention discloses a controller for a flow generator to supply breathable gas cyclically at an inspiration pressure and at a lower expiration pressure substantially in synchronism with the patient's respiration, the controller comprising:

data processing means for receiving an input respiratory flow signal and for  
10 detecting transitions between inspiration and expiration from said flow signal to discriminate between patient inspiration and expiration, and for outputting a control signal to the flow generator to set the inspiratory pressure and the expiratory pressure, and

timer means operable to select a time duration commencing from the last  
15 transition to inspiration whereby if said first time inspiratory duration elapses before the data processing means detects a transition to expiration by the patient, the output signal from the data processing means causes the flow generator to supply said expiration pressure.

The time duration can be user adjustable. In another form, there is provided a  
20 second time duration commencing from the last transition to inspiration corresponding to the data processing means forcing said flow generator to supply said inspiration pressure until said second time duration elapses even if during said second time duration there is a transition to expiration by the patient. Furthermore, data processing means can periodically update said first time duration based on one or more subsequent  
25 respiratory transitions to expiration and whether the first time duration elapses before one or more of said subsequent transitions occur, to converge the elapse of said first time duration with said subsequent transitions to expiration.

The invention further discloses CPAP or assisted respiration apparatus comprising a controller as described above, a flow generator coupled to the controller

for supplying breathable gas to a gas delivery system providing the breathable gas to the patient's airway, and a flow sensor located in said gas delivery system.

The invention further discloses a method for controlling the supply of breathable gas to a patient cyclically at an inspiration pressure and at a lower expiration pressure substantially in synchronism with the patient's respiration, the method  
5 comprising the steps of:

- (a) measuring patient respiratory flow;
- (b) detecting transitions between inspiration and expiration from said respiratory flow to discriminate between patient inspiration and expiration;
- 10 (c) controlling the pressure of gas to be at the inspiration pressure during patient inspiration and at the expiratory pressure during patient expiration; and
- (d) prescribing a first time duration commencing from the last transition to inspiration by the patient, and if a said duration elapses before patient transition to expiration, causing the pressure of gas to be at the expiratory pressure.

15 Preferably, the method comprises the further step of:

- (e) prescribing a second time duration commencing from the last transition to inspiration, and causing the pressure of gas to be at the inspiratory pressure until the elapse of said second time duration even if there is a transition to expiration by the patient during the second time duration.

20 Yet further, there can be the further step of :

- (f) updating said first time duration based on one or more previous respiratory transitions to expiration and whether the first time duration elapses before one or more of said previous transitions occur to converge the elapse of said first time duration with said previous transitions to expiration.

25 The provision of a variable maximum inspiratory treatment pressure duration is advantageous in maintaining synchronism between CPAP apparatus and a patient's breathing, thereby maintaining efficacy of the treatment and ensuring that the workload of breathing is not increased. This is particularly so for those patients who exhibit mouth-leak during IPAP.

For a small percentage of patients receiving CPAP treatment, for example those with REM hypoventilation, only small inspiratory effort is made. Under the bilevel regime, it is conventionally the case that because of the small inspiratory effort the CPAP apparatus will make a transition to EPAP while the patient still is inspiring.

5 Thus an advantage of a variable minimum inspiratory duration is that the patient does not have to make a sustained respiratory effort in order that the IPAP pressure be maintained. Adequate ventilation or respiratory assistance therefore can be assured. Further, the ability to vary the minimum IPAP duration enables the physician to match the therapy to the patient's normal breathing whilst asleep.

10 An advantage of the automatic adjustment of the maximum IPAP duration is that variations in a patient's breathing, which might occur overnight, seasonally or with disease progression, can be accounted for and near synchronism with the patient's respiration maintained.

#### 15 **Brief Description of the Drawings**

Embodiments of the invention now will be described with reference to the accompanying drawings, in which:

Fig. 1 is a schematic block diagram of bilevel CPAP apparatus;

Fig. 2 is a functional block diagram of a respiration detection circuit  
20 incorporating variable maximum IPAP duration;

Figs. 3a to 9b show clinical data of respiratory flow and bi-level CPAP treatment pressure for a number of patients with and without maximum IPAP duration;

Fig. 10 is a functional block diagram of a respiration detection circuit incorporating a variable minimum IPAP duration; and

25 Fig. 11 is a functional block diagram showing automatic adjustment of IPAP duration.

### Description of Preferred Embodiments and Best Mode

The embodiments described relate to CPAP apparatus and treatment, however, the invention is to be understood as being equally applicable to assisted respiration devices. Referring then to Fig. 1, the CPAP apparatus comprises a flow generator 10 coupled by a flexible delivery tube or conduit 12 to, in this case, a nose mask 14 worn by a patient 16. The flow generator 10 broadly comprises an electric motor 18 that is powered by a motor power supply 20. In turn, the electric motor 18 has mechanical coupling with a turbine 22 that outputs either air or breathable gas at a pressure elevated above atmospheric pressure to the delivery tube 12. The output delivery pressure from the turbine 22 is governed by the rotational speed of the electric motor 18, the speed therefore being the controlled variable relative to the desired CPAP treatment pressure. The motor 18 speed is controlled by the motor controller 23 which effects changes in motor speed by means of a control signal on control line 24 provided to the motor power supply 20. Thus motor speed is controlled by means of varying the motor power supply 20.

The motor controller 23 receives an electrical signal on control line 26 representative of, in this case, delivery pressure from the turbine 22 as measured by the pressure transducer 28 which is connected via a sensing line 29 to a sensing port 27 proximate to the turbine outlet. The sensing of delivery pressure is important in maintaining regulation of treatment pressure.

An inline flow transducer 34 also is provided near the outlet to the turbine 22, and supplies a flow signal to the motor controller 23 on line 36. The function of the flow sensor will be presently described.

In one preferred form, the motor 25 driving the turbine 22 can be a PAPST™ ECA 27-11 brushless DC motor. Being a DC motor, its speed is directly proportional to the armature voltage. The particular motor described has integral Hall-effect sensors, thus providing a measure of motor angular rotational speed required for speed (and hence delivery pressure) regulation, that signal being output from the motor 18 to the motor controller 22 on control line 30.



The pressure transducer 28 can be such as a Motorola™ MPX 2010DP type. The flow transducer can be such as a Micro Switch™ AWM2200V type. The motor controller 23 can be implemented by any commercially available microprocessor, although one preferred form is the 8-bit Motorola™ MC68HC805B6 micro-controller.

5 As briefly described above, bilevel CPAP treatment controls the pressure of the air or breathable gas supplied to the entrance of the patient's airway as a higher inspiratory pressure in phase with the patient's inspiration, and a lower expiratory pressure in phase with the patient's expiration. Typical differences between the IPAP and EPAP treatment pressures are 6-12 cm H<sub>2</sub>O. In order to implement bilevel CPAP  
10 treatment, it is necessary to detect the transitions between patient inspiration and expiration so that the IPAP and EPAP treatment pressures can be in synchronism with the respective phases of respiration. Such transitions are detected by means of the flow transducer 34, in that a zero crossing or threshold value can be discriminated as a trigger to a transition event. In this regard, reference can be had to the bilevel CPAP  
15 apparatus commercially available from the present applicant and sold under the trade mark "VPAP".

Fig. 1 also shows a set of controls 38, which can be in the form of potentiometers, pushbuttons or the like for manual adjustment of parameters relating to IPAP duration. The controls may be located within the casing of the CPAP apparatus  
20 so as only to be accessed by a physician or trained technician, or in the alternative they may be generally accessed from outside of the casing for free manipulation by a patient directly or by a physician or technician.

Fig. 2 is a functional block diagram that represents logic elements, typically implemented by one or more computer programs, within the motor controller 23. The  
25 signal representative of flow on line 36 is input to a low pass filter 40 typically having an upper limiting frequency of 20 Hz and intended to remove noise in the flow signal. The output of the low pass filter is supplied to a high pass filter 42, typically having a lower limiting frequency of 0.5 Hz that removes non-respiratory components of the signal. The output of the high pass filter then is supplied to a band-limited

differentiator 44, the output of which thus represents the time rate of change of the flow signal. The output of the differentiator 44 is provided to separate comparators 46,48. Associated with each of the comparators 46,48 is a respective threshold reference unit 50,52. The comparators and respective threshold reference units relate to the separate  
5 detection of inspiration and expiration so as to control the supplying of IPAP and EPAP treatment pressure to a patient.

The comparator 46 thus compares the time differentiated and filtered flow signal with a threshold reference from the threshold reference unit 50, and when the threshold is exceeded (in the negative sense) an "inhalation detection signal" 54 is  
10 generated. That is, the occurrence of negative gradient in the flow signal represents a transition to inspiration. Conversely, a positive gradient in the flow signal represents a transition to expiration. In that case, the reference threshold supplied by the threshold reference unit 52 to the comparator 48 is positive, with the output 56 from the comparator 48 representing an "exhalation detection signal" being provided to a logic  
15 unit 60.

The inhalation detection signal 54 is passed to a counter 58, which is in the nature of a resettable timer that determines the duration for which the inhalation detection signal 54 has been active. The output of the counter is provided to the logic unit 60.

20 The controls 38 also provide an input to the logic unit 60, by which the maximum allowable IPAP duration (time-out) can be set. The duration/time-out typically will be set to the patient's prevailing inspiratory time. In this way, the logic unit 60 watches the state of the counter 58 following commencement of a patient inspiration, and if the counter does not reset (for reason of a transition to expiration)  
25 before the elapse of the maximum duration/time-out set by the controls 38, then the logic unit 60 forces a change to the EPAP state. An output of the logic unit 60 therefore is an EPAP control signal that has control over the state of operation of the CPAP apparatus as to provision of either EPAP treatment pressure. Conversely, the other output to the logic unit 60 is an IPAP control signal. Selection, control and

regulation of the respective EPAP and IPAP treatment pressures is performed by other logic units of the motor controller 23 in the conventional manner.

In all of Figs. 3a-9b the clinical traces denominated "a" represent approximate respiratory flow rate. The convention adopted is that negative flow equates to inspiration, and as follows, positive flow relates to expiration. The traces denominated "b" represent CPAP treatment pressure. The treatment is in the nature of bi-level CPAP, with the higher treatment pressure intended to correspond with patient inspiration, and the lower treatment pressure intended to correspond with patient expiration. The duration of the inspiratory and expiratory portions of the CPAP treatment are as provided by bi-level CPAP apparatus, such as the present applicant's "VPAP" apparatus, that seek to maintain synchrony with transitions in the patient's respiration. Thus the respective duration of the inspiratory and expiratory portions of the CPAP treatment can be seen to vary in time.

The patient from whom the respiratory traces shown in Figs. 3a and 3b were made suffers from OSA and REM (Rapid Eye Movement) hypoventilation. A study of the respective flow and pressure traces reveals asynchrony following the third, fourth, fifth and sixth transitions from IPAP to EPAP. This is a pattern that is due essentially to mouth leak, and can at times result in patient arousal. Such asynchrony can, in some patients, lead to ineffective ventilation and may increase the work of breathing.

The traces shown in Figs. 5a and 5b are for the same patient as for Figs. 3a-4b, however with maximum IPAP duration being practiced. As can be noted, there is a dramatic improvement in the synchronism of the patient's respiration with treatment pressures.

The traces shown in Figs. 6a-7b relate to a patient having severe lung disease. As can be seen from Figs. 6a and 6b, the duration of and time of transition between the IPAP and EPAP treatment pressures are only poorly in synchronism with the patient's respiration. Figs. 7a and 7b show an improved synchronism where maximum IPAP duration is in effect.

Figs. 8a-9b relate to a separate patient suffering severe lung disease. Figs. 8a and 8b show the event of the maximum IPAP duration being defeated with the subsequent immediate asynchronous nature of the patient's respiration. The traces of Figs. 9a and 9b show an example of respiration and treatment pressure showing a high degree of synchronism with maximum IPAP duration in effect.

Fig. 10 is a slightly modified form of the arrangement shown in Fig. 2, in that the output from the comparator 46, indicative of a transition to inspiration (the commencement of inspiration) also is provided to the logic unit 60. Furthermore, a second counter 62 is provided, also receiving the output from the comparator 46 and, in turn, its output being provided to the logic unit 60. The counter 62 is free-running, in the sense that it is not resettable in the absence of continuing inspiration, manifested by a negative gradient in the flow signal. The controls 38 also include the facility for selecting the minimum IPAP duration, which is provided to the logic unit 60. The minimum duration typically will be set at 300 ms, meaning that following sensing of commencement of inspiration, even if the output of the comparator 46 changes in response to detect a change to expiration, the IPAP state will be forced by the logic unit 60 until expiration of the 300 ms minimum duration determined from the counter 62. Thus the logic unit 60 gives precedence to the signal provided by the second counter 62 ignoring any resetting of the first counter 58 until the minimum duration has elapsed.

The embodiment shown in Fig. 10 thus provides the function of having a selectable minimum IPAP duration following detection of commencement of inspiration regardless of any sensed change to expiration, and has a maximum duration/time-out that forces a change to EPAP treatment in the absence of any earlier sensed change of state to expiration. The counter 62 is automatically reset when it reaches its maximum value.

Fig. 11 shows an arrangement for the automatic adjustment of the maximum IPAP duration/time-out that is a modification of the arrangement shown in Fig. 10. In this way, the time-out period can automatically adjust to account for variations in a patient's breathing. The output from the resettable counter 58 is provided to a further

comparator 64. The counter 58 has the same role as before in counting time since the last transition to inspiration. The signal 66 fed-back from the logic unit 60 to the comparator 64 represents the "current IPAP time-out" value, and this is compared with the counter value by the comparator 64. The output from the comparator 64 will  
5 change state when the current IPAP time-out value elapses and there has been no detection of a transition to expiration, in which case there will be an incremental increase of the current IPAP time out towards the maximum time-out limit specified by the relevant storage unit 68. In the event that the counter 58 times-out in advance of the current IPAP time-out value, then the logic unit 60 will attempt to adapt the current  
10 IPAP time-out value by way of reduction in an incremental manner towards the minimum time-out limit set by the relevant storage unit 70. Indicative minimum and maximum time-out limits are 300 ms and 3 seconds. The maximum and minimum time-out limits held by the respective storage units 68,70 can be set by the physician using a potentiometer or other input means. Alternatively, default values can be used.  
15 In this manner, the current IPAP time-out value will be continuously updated to be close to the patient's prevailing inspiratory time, so that if the transition to inspiration is not detected or triggered for whatever reason, the time-out period will be closest to the normal period, and so a change to EPAP treatment pressure will result still substantially in synchronism with the patient's respiration.

20 Clearly, one, two or all of the embodiments can be implemented for the control of CPAP or assisted respiration apparatus and fall within the broad scope of the present invention.

**CLAIMS:**

1. A controller for a flow generator to supply breathable gas cyclically at an inspiration pressure and at a lower expiration pressure substantially in synchronism  
5 with the patient's respiration, the controller comprising:

data processing means for receiving an input respiratory flow signal and for detecting transitions between inspiration and expiration from said flow signal to discriminate between patient inspiration and expiration, and for outputting a control signal to the flow generator to set the inspiratory pressure and the expiratory pressure;  
10 and

timer means operable to select a first time duration commencing from the last transition to inspiration, whereby if said first time duration elapses before the data processing means detects a transition to expiration by the patient, the output signal from the data processing means causes the flow generator to supply said expiration pressure.  
15

2. A controller as claimed in claim 1, wherein said timer means is at least user adjustable.

3. A controller as claimed in claim 1, further comprising a second time  
20 duration commencing from the last transition to inspiration corresponding to the data processing means forcing said flow generator to supply said inspiration pressure until said second time duration elapses even if during said second time duration there is a transition to expiration by the patient.

25 4. A controller as claimed in claim 3, wherein said data processing means periodically updates said first time duration based on one or more subsequent respiratory transitions to expiration and whether the first time duration elapses before one or more of said subsequent transitions occur to converge the elapse of said first time duration with said subsequent transitions to expiration.

5. A controller as claimed in claims 3 or 4, wherein said second time duration is shorter or equal to said first time duration.

5 6. A controller as claimed in any one of the preceding claims, wherein said data processing means comprises means for differentiating said respiratory flow signal, the polarity of the differentiated signal representing either inspiration or expiration.

10 7. A flow generator for supplying breathable gas cyclically at an inspiration pressure and a lower expiration pressure substantially in synchronism with the patient's respiration, the flow generator comprising:

a turbine to pressurise inlet breathable gas;

a variable speed electric motor to control operation of said turbine and thus the  
15 pressure of breathable gas delivered by the turbine; and

a controller as claimed in any one of the preceding claims, in which said data processor means outputs said control signal to said motor.

8. Apparatus for the supply of breathable gas cyclically at an inspiratory  
20 pressure and a lower expiratory pressure substantially in synchronism with the patient's respiration, the apparatus comprising:

a flow generator as claimed in claim 7;

a gas delivery system coupled to the flow generator and providing said  
breathable gas to the patient's airway; and

25 a flow sensor located in said gas delivery system and coupled to said data processing means to provide said input respiratory flow signal therefrom.

9. Apparatus as claimed in claim 8, wherein said gas delivery system comprises a nose and/or face mask coupled to a flexible conduit.

10. A method for controlling the supply of breathable gas to a patient cyclically at an inspiration pressure and at a lower expiration pressure substantially in synchronism with the patient's respiration, the method comprising the steps of:

- 5 (a) measuring patient respiratory flow;
- (b) detecting transitions between inspiration and expiration from said respiratory flow to discriminate between patient inspiration and expiration;
- (c) controlling the pressure of gas to be at the inspiration pressure during patient inspiration and at the expiratory pressure during patient expiration; and
- 10 (d) prescribing a first time duration commencing from the last transition to inspiration by the patient, and if a said duration elapses before patient transition to expiration, causing the pressure of gas to be at the expiratory pressure.

11. A method as claimed in claim 10, comprising the further step of:

- 15 (e) prescribing a second time duration commencing from the last transition to inspiration, and causing the pressure of gas to be at the inspiratory pressure until the elapse of said second time duration even if there is a transition to expiration by the patient during the second time duration.

12. A method as claimed in claim 11, comprising the further step of:

- 20 (f) updating said first time duration based on one or more subsequent respiratory transitions to expiration and whether the first time duration elapses before one or more of said subsequent transitions occur to converge the elapse of said first time duration with said subsequent transitions to expiration.

25

13. A method as claimed in claims 11 or 12, whereby step (b) further comprises differentiating a signal of said respiratory flow, the polarity of the differentiated signal representing either inspiration or expiration.



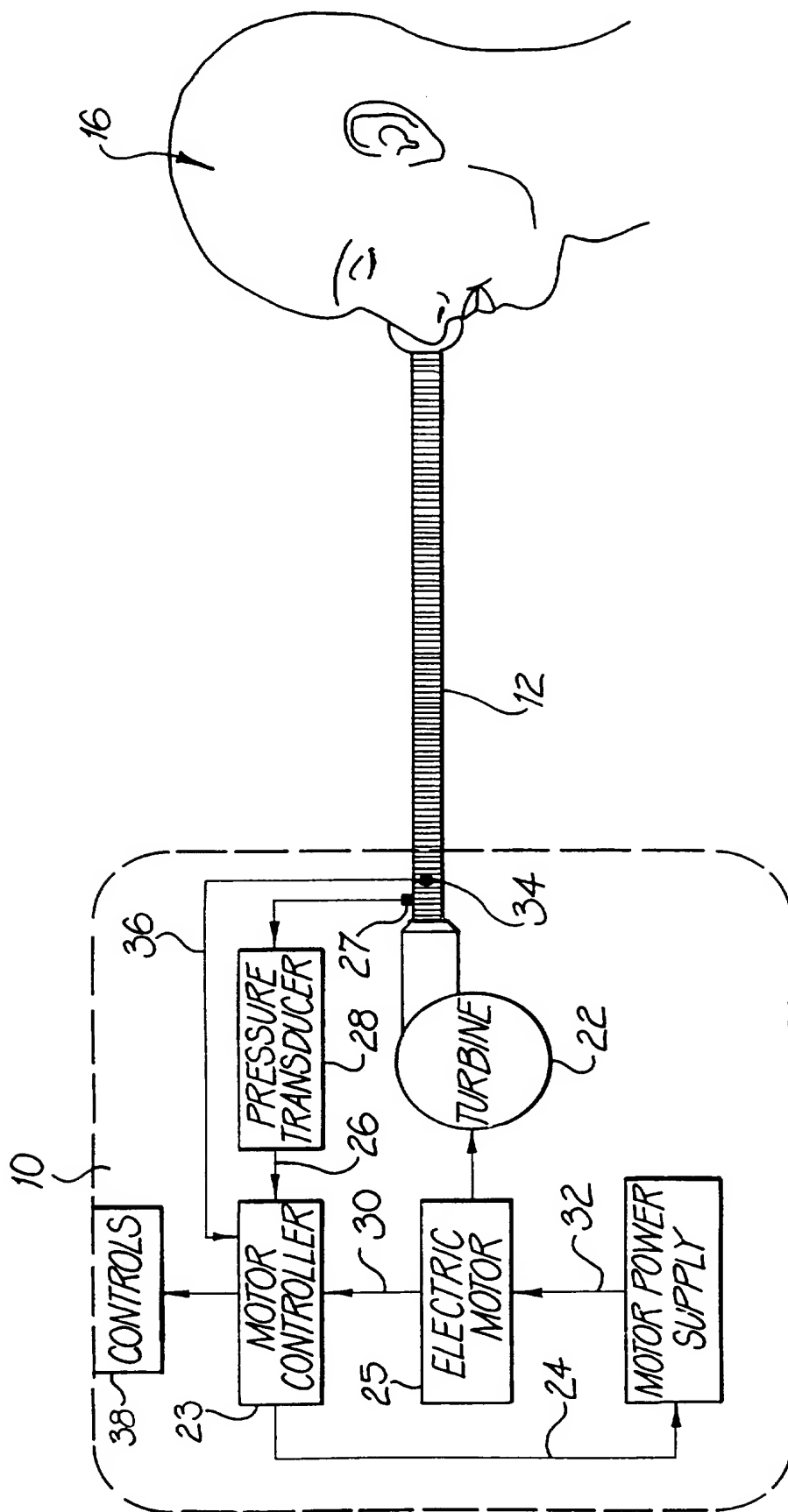


FIG. 1

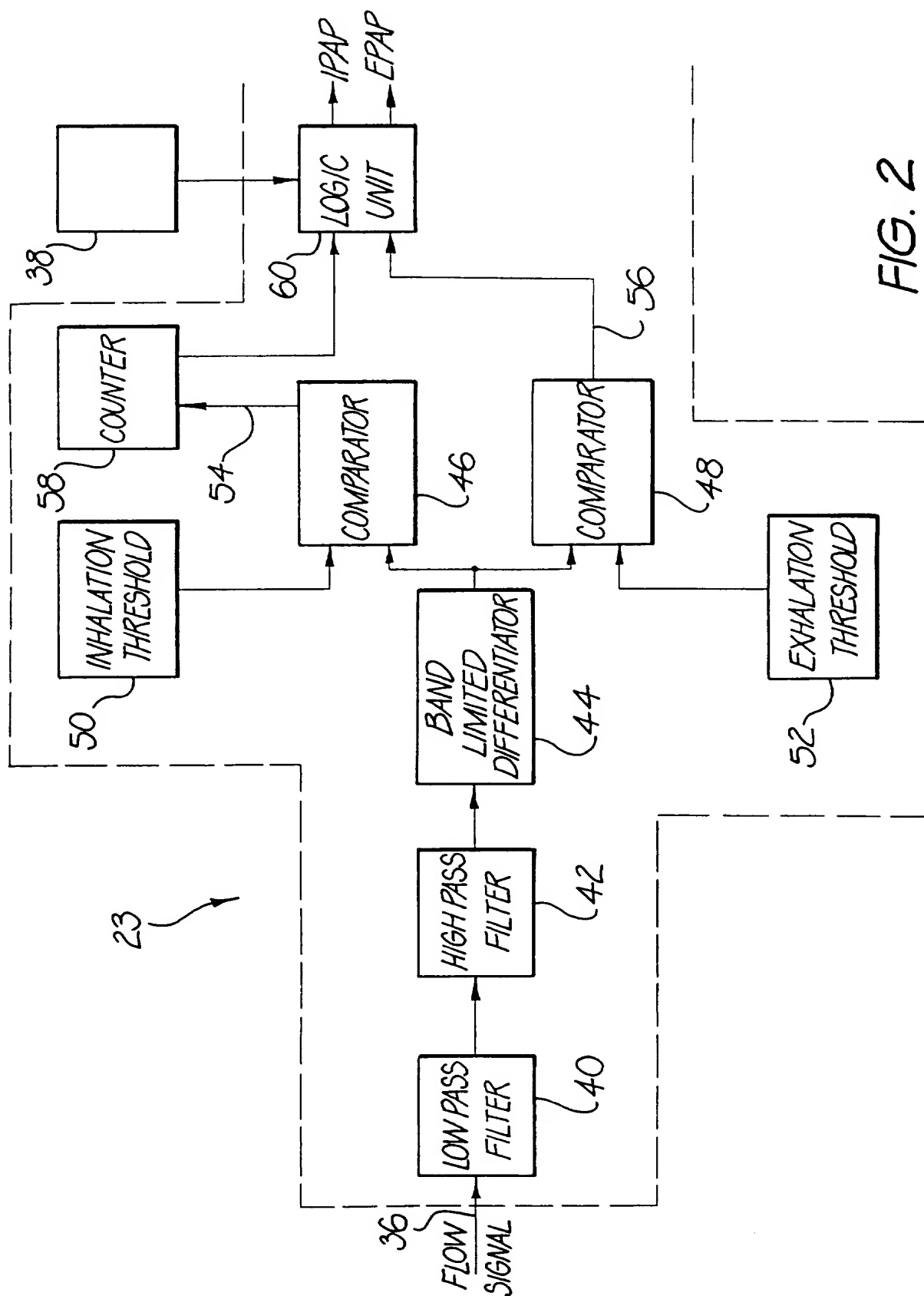
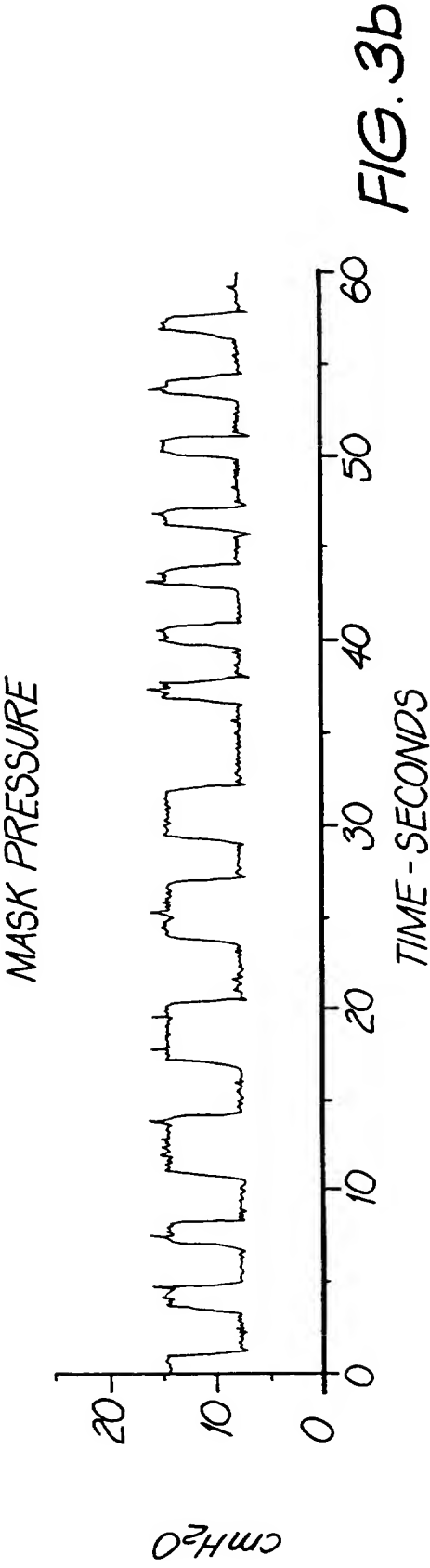
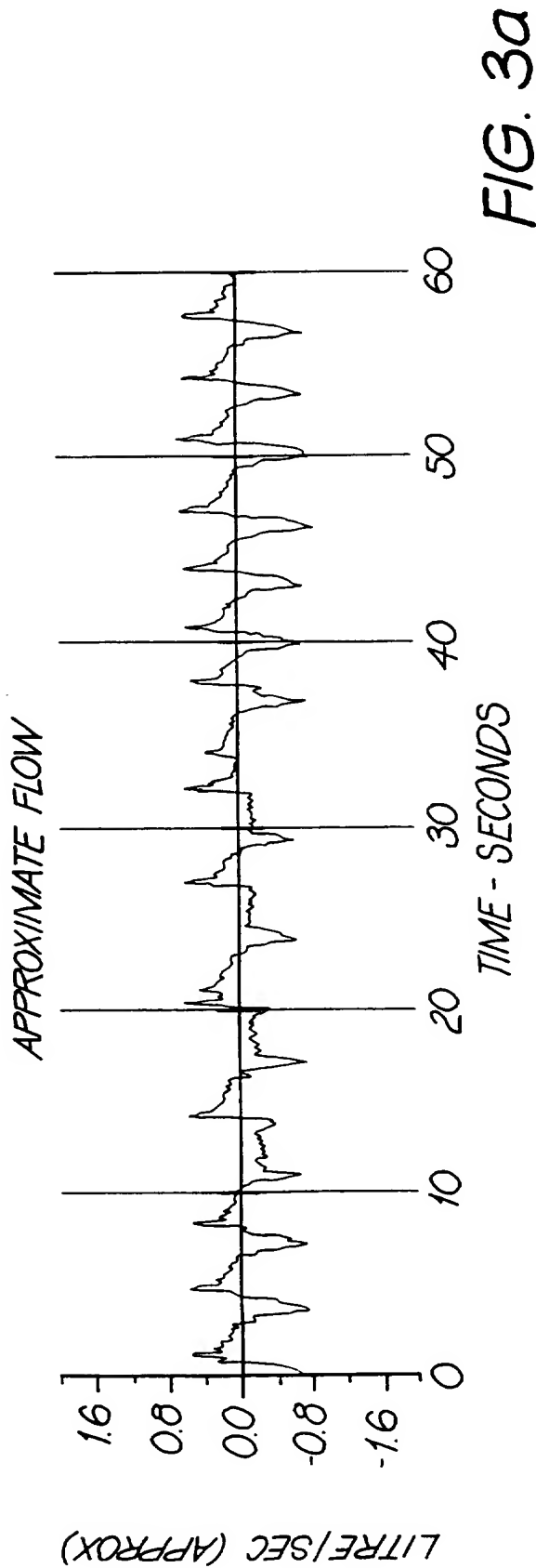
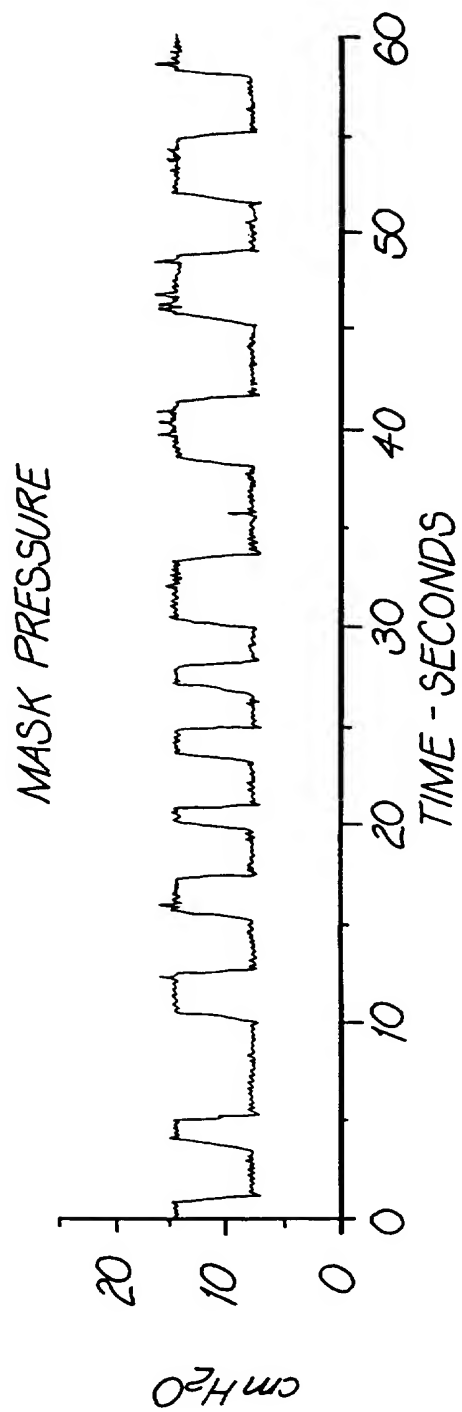
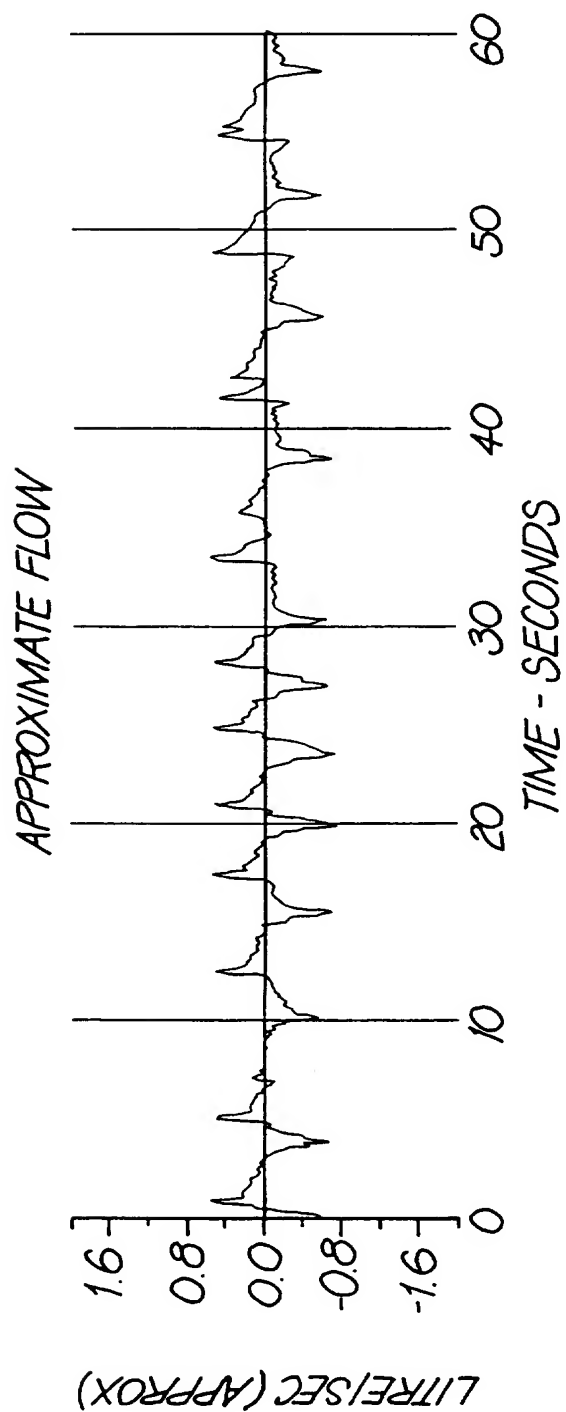
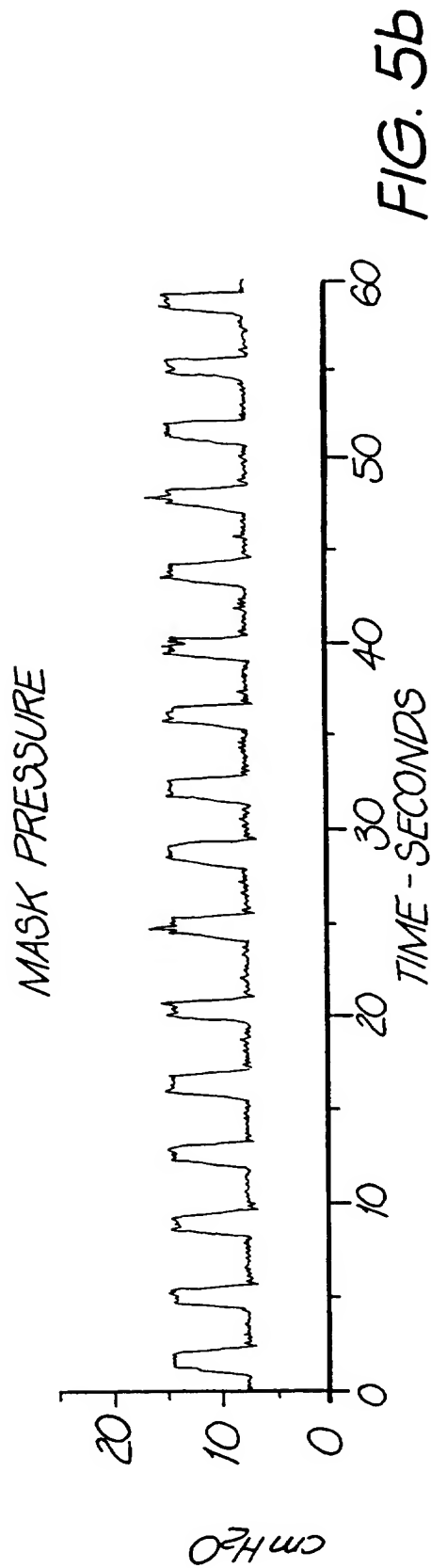
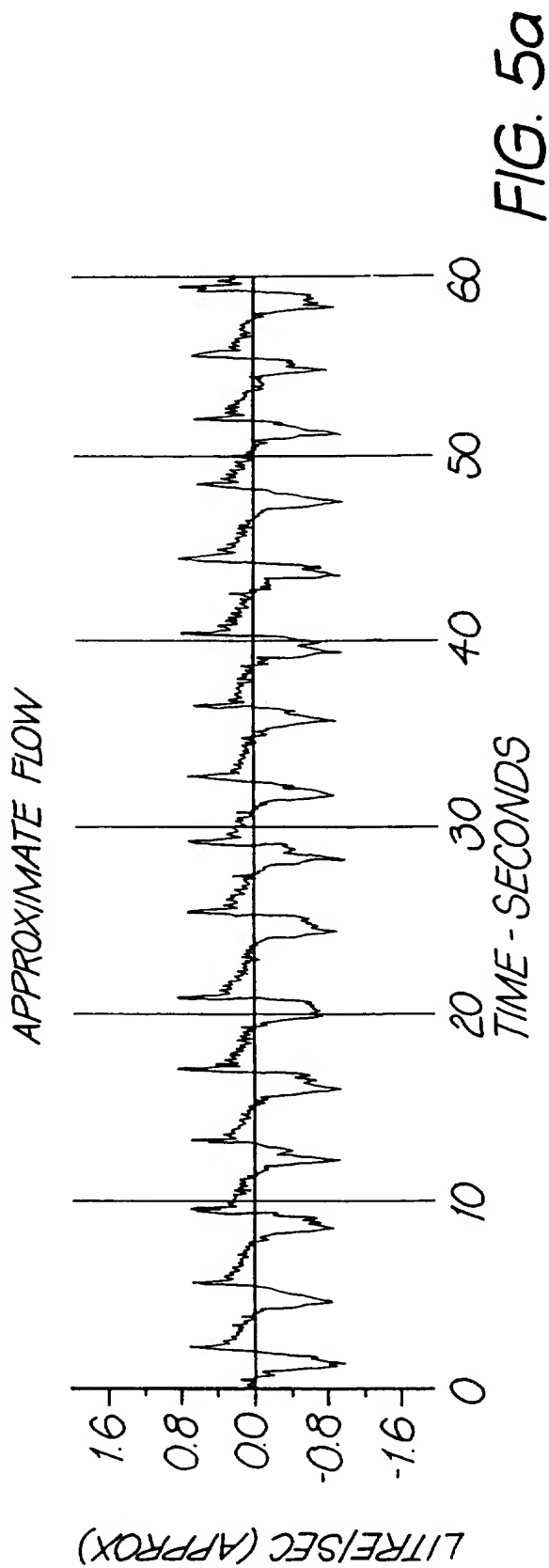


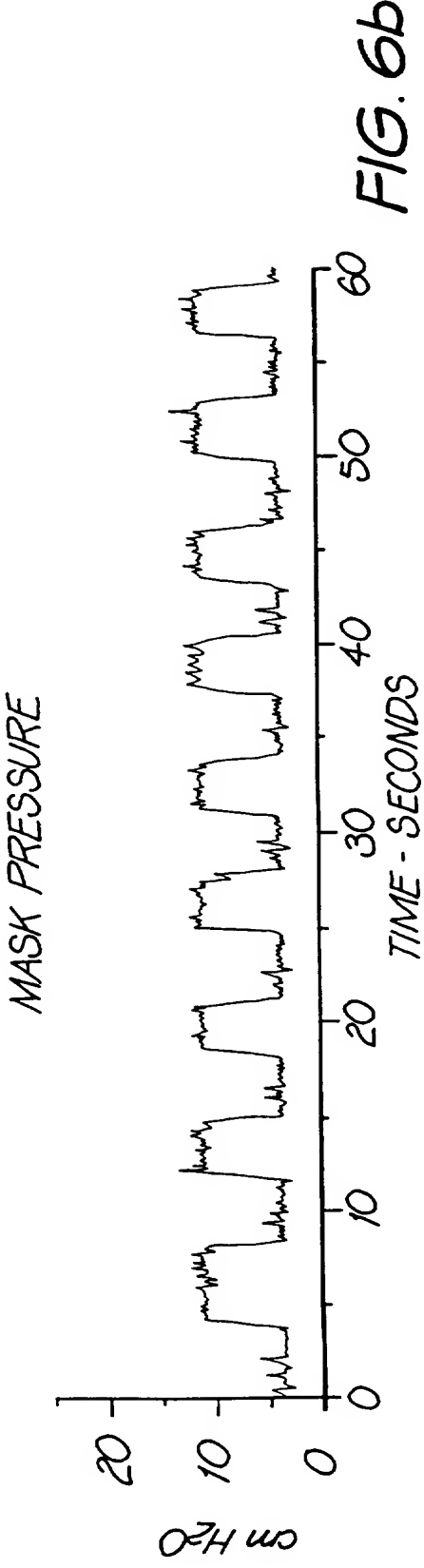
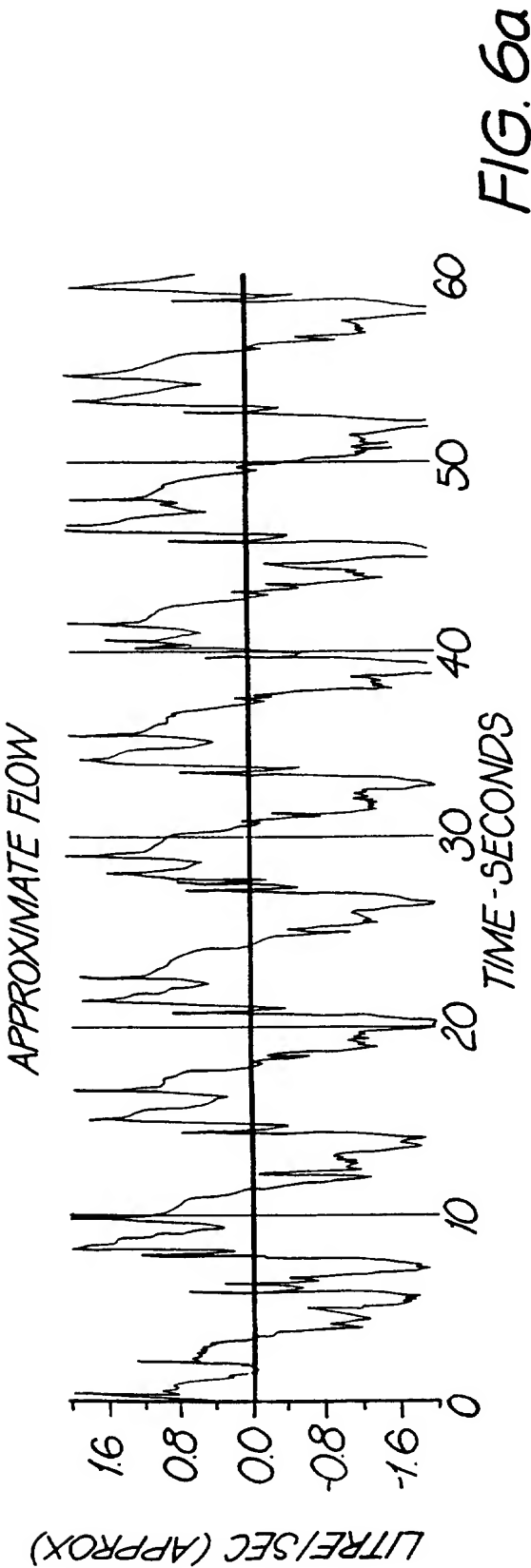
FIG. 2

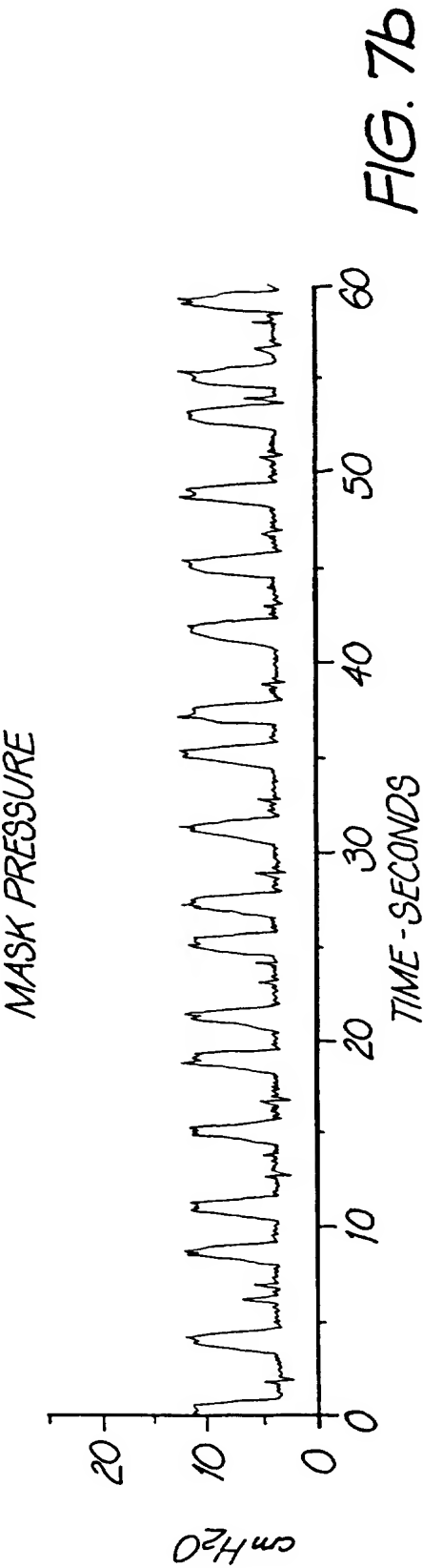
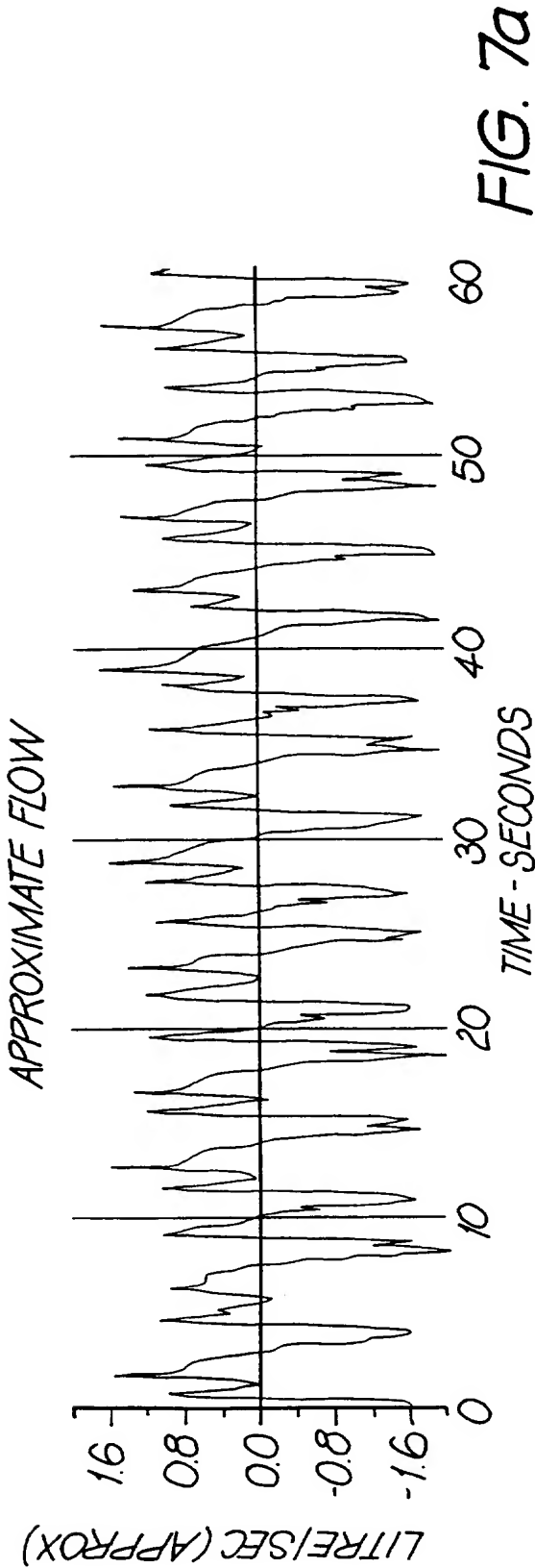


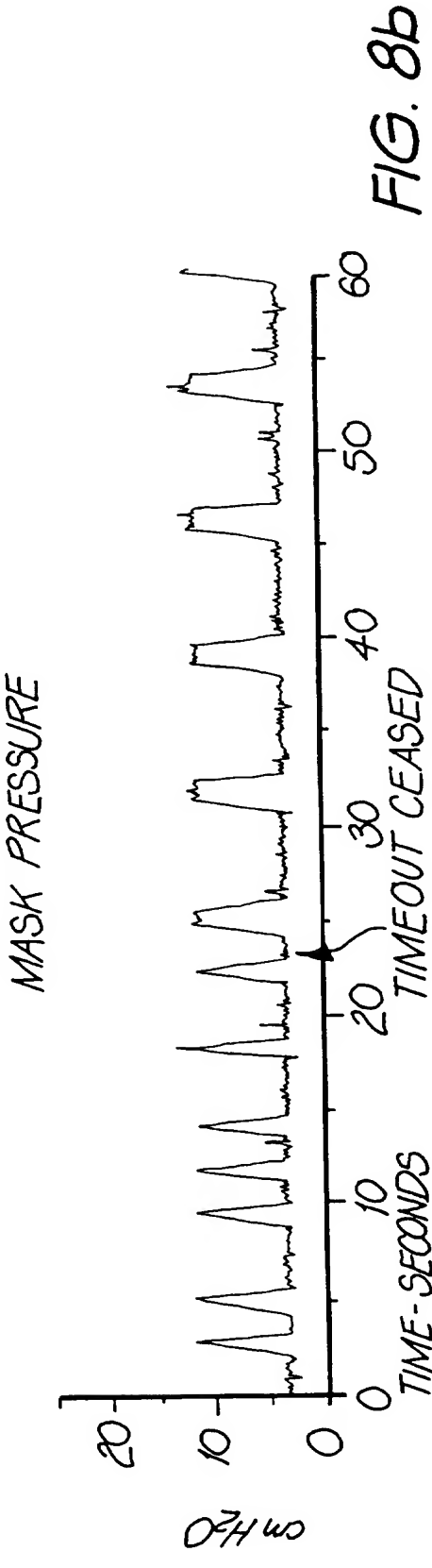
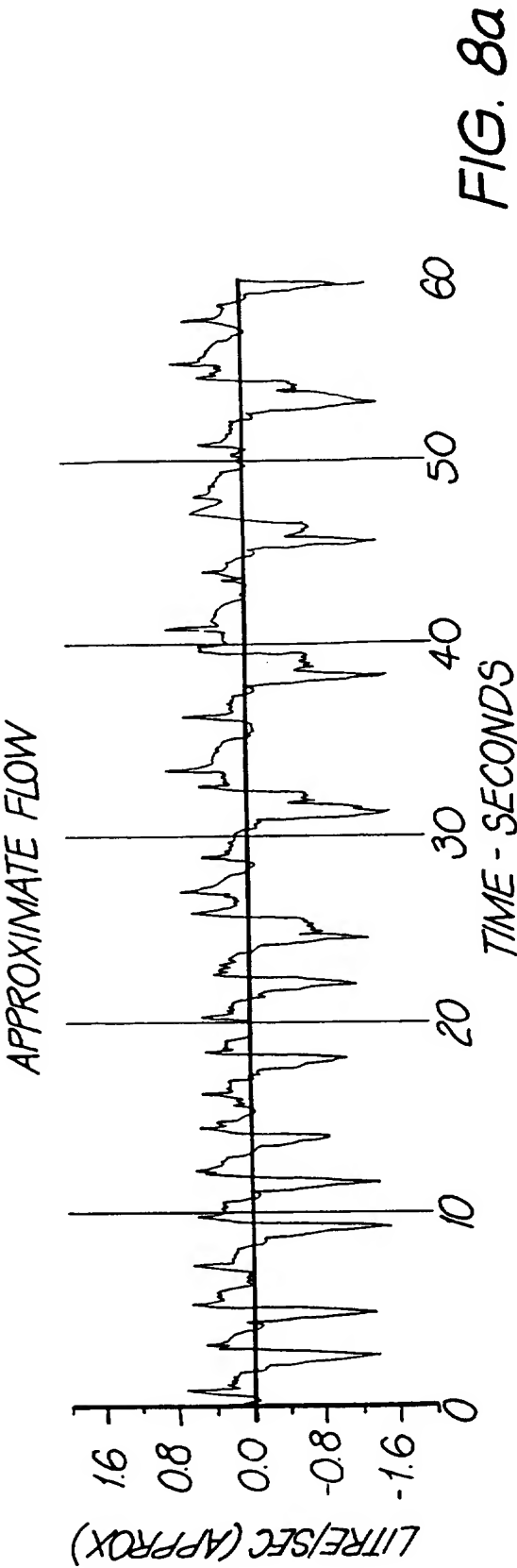


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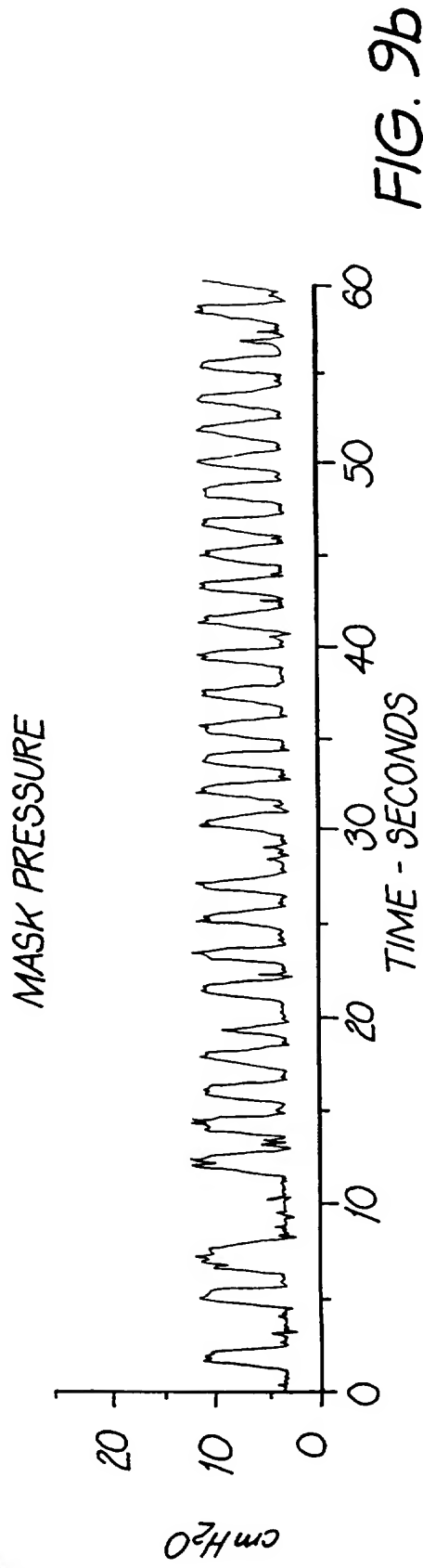
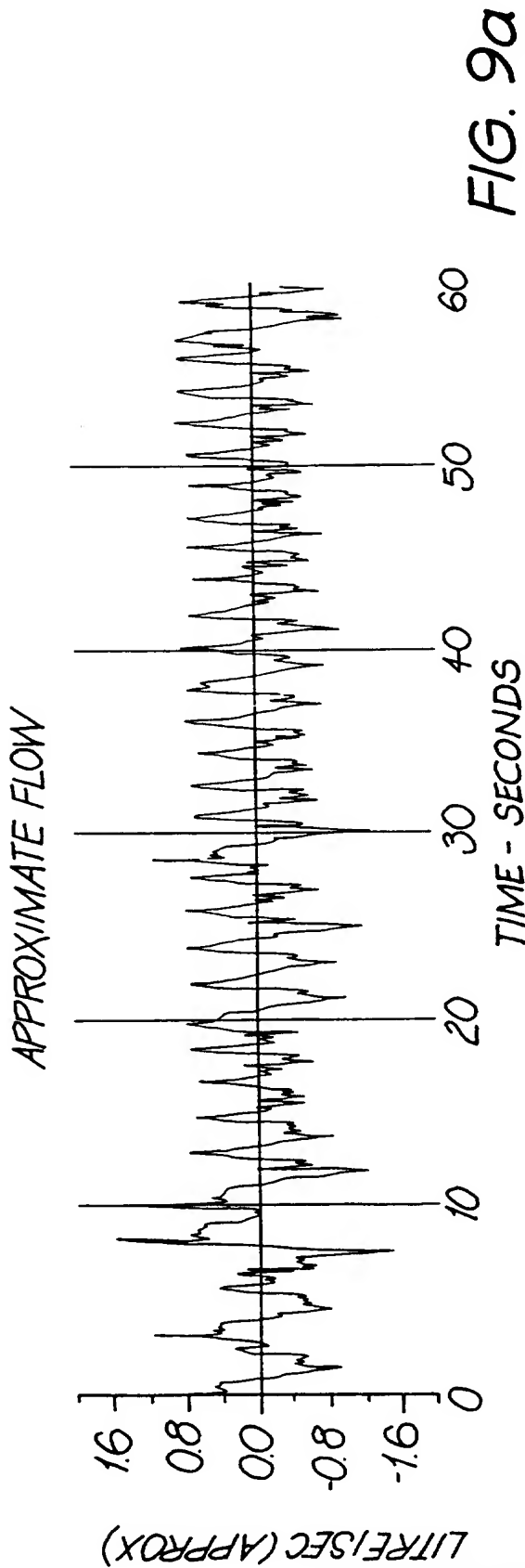








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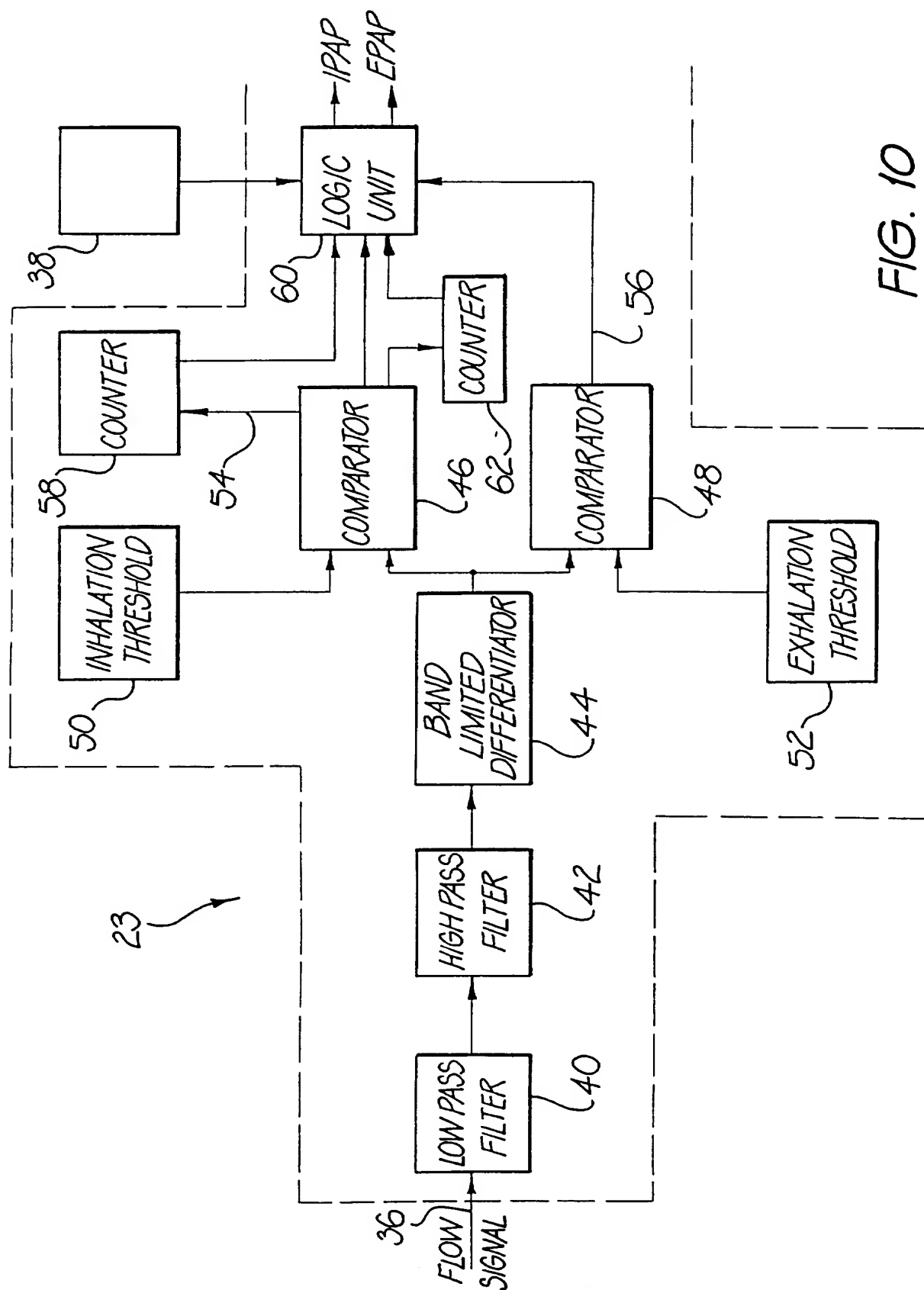


FIG. 10

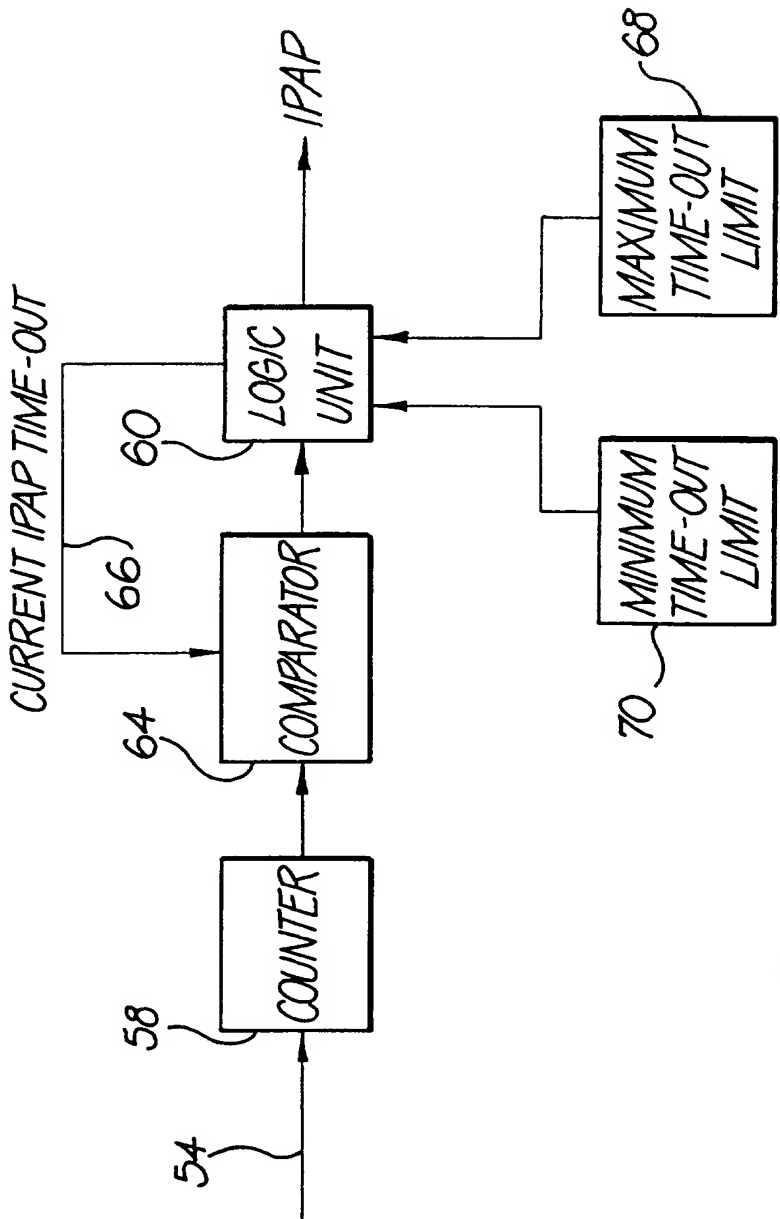


FIG. 11

# INTERNATIONAL SEARCH REPORT

International Application No.

PCT/AU 96/00652

## A. CLASSIFICATION OF SUBJECT MATTER

Int Cl<sup>6</sup>: A61M 16/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC A61M 16/00

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched  
AU: IPC as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPAT & JAPIO A61M 16/-, F04B 49/-, A62B 7/-, G01F 1/-, 15/- + keywords

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 94/23780 A1 (RESPIRONICS), 27 October 1994 lines 19-27, page 10	
A	WO 86/06969 A1 (ETELA-HAMEEN KEUHKOVAMMAYHDISTYS R.Y.), 4 December 1986	
A	JP 63275352 A (KAZUHIKO MURAMATSU), 14 November 1987	

☒ Further documents are listed in the continuation of Box C

☒ See patent family annex

<p>* Special categories of cited documents:</p>		
"A"	document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P"	document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 5 December 1996	Date of mailing of the international search report 17 Dec 1996
Name and mailing address of the ISA/AU AUSTRALIAN INDUSTRIAL PROPERTY ORGANISATION PO BOX 200 WODEN ACT 2606 AUSTRALIA Facsimile No.: (06) 285 3929	Authorized officer  A.R. HENDRICKSON Telephone No.: (06) 283 2415

**INTERNATIONAL SEARCH REPORT**

International Application No.

**PCT/AU 96/00652**

<b>C (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
<b>Category*</b>	<b>Citation of document, with indication, where appropriate, of the relevant passages</b>	<b>Relevant to claim No.</b>
A	DE 3429345 A1 (DRAGERWERK AG), 13 June 1985	
A	GB 1583273 A (MEDISHIELD CORPORATION LIMITED), 21 January 1981	
A	WO 94/22517 A1 (THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA) 13 October 1994	

**INTERNATIONAL SEARCH REPORT**  
**Information on patent family members**

International Application No.  
**PCT/AU 96/00652**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	9423780	AU	66296/94	CA	2159336	EP	699085
		US	5458137	AU	21892/92	CA	2111324
		EP	592492	US	5203343	WO	9222244
WO	8606969	FI	852073	GB	2189706	NO	870272
		SE	8700227	SU	1745104	US	4986269
JP	63275352						
DE	3429345	EP	148320	JP	60139261	US	4667669
		SU	1489575				
GB	1583273	AU	35773/78				
WO	9422517	AU	65296/94				
END OF ANNEX							